

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Purl, M.D., et al.,

Plaintiffs,

v.

**United States Department of
Health and Human Services, et al.,**

Defendants.

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Civil Action No. 2:24-cv-228-Z

**REPLY IN SUPPORT OF PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

HHS’s 2024 Rule¹ contradicts HIPAA’s statutory rule of construction, improperly redefines statutory terms, and lacks any basis in the statutory delegation of authority. HIPAA protects the privacy of *all* PHI—it authorizes no content-based regime for PHI reflecting “reproductive health care.” The 2024 Rule should be held unlawful and set aside.

Defendants do not address the merits in their opposition, limiting their argument to other issues.² *First*, they contend Dr. Purl and her Clinic (“Dr. Purl,” or “Plaintiffs”) lack standing to challenge a regulation that directly regulates them. That argument is untenable under well-settled APA doctrine. *Second*, Defendants contend the unlawful regulation should not be vacated—the default remedy under the APA—and any remedy should be limited to Dr. Purl and her Clinic. That argument is foreclosed by Fifth Circuit precedent. *Finally*, Defendants generically argue for severing provisions of the 2024 Rule, but they fail to show that any of the provisions derived from HHS’s “reproductive health care” proposed rule could be retained.³ Thus, other than a few paragraphs derived from a separate proposed rule concerning substance use disorder treatment,⁴ the 2024 Rule should be set aside.

¹ HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024).

² The proposed intervenors also filed a brief, ECF No. 69, even though the Court has not granted them intervenor status. Plaintiffs’ view is that the proposed intervenors’ brief was improperly filed and does not implicate a reply. This brief, however, addresses a few points that are relevant to those arguments as well.

³ HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 88 Fed. Reg. 23,506 (proposed Apr. 17, 2023).

⁴ Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74,216 (proposed Dec. 22, 2022).

ARGUMENT

I. Plaintiffs have Article III standing.

As Plaintiffs have already discussed, Dr. Purl and her Clinic have Article III standing. They are objects of the 2024 Rule and thus have standing to challenge it under the APA. They also will incur compliance costs, which is itself an injury in fact. *See* Pls.’ Br. [ECF No. 45] at 18–19; Pls.’ Opp. [ECF No. 66] at 10–12.⁵

A. Objects of a regulation have standing to sue.

Defendants’ arguments against standing (at 2–4) conspicuously fail to mention the fundamental doctrine of APA standing: objects of a regulation have standing to sue.⁶ “[R]egulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements.” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). Dr. Purl has already discussed the ways the 2024 Rule requires and forbids her action. *See* Pls.’ Opp. at 8.

The Fifth Circuit applies this standard. The “basic question” is “whether the plaintiff is himself an object’ of the challenged regulation.” *Contender Farms, LLP v. USDA*, 779 F.3d 258, 264 (5th Cir. 2015) (quoting *Lujan*, 504 U.S. at 561). Answering that question is a matter of “common sense.” *Id.* at 265. Being “bound by the terms” and “inspection procedures” of a rule is enough, even if whether the rule “actually” applies to plaintiffs in particular cases is a matter of “disagree[ment].” *Id.*

⁵ This brief uses the notation “Pls.’ Opp. at []” to refer to Plaintiffs’ opposition brief, ECF No. 66. As before, “Pls.’ Br. at []” refers to Plaintiffs’ Brief in Support of Motion for Summary Judgment, ECF No. 45, and “Defs.’ Br. at []” refers to Defendants’ Brief in Support of Motion to Dismiss or, in the Alternative, for Summary Judgment, ECF No. 40.

⁶ Unless otherwise noted, citations to Defendants’ arguments are to page numbers in Defendants’ Opposition to Plaintiffs’ Motion for Summary Judgment, ECF No. 70, which is also cited as “Defs.’ Opp. at [].”

at 266. So when participants in the Tennessee Walking Horse industry challenged a USDA regulation requiring particular inspection procedures and sanctions for violating the Horse Protection Act, the Fifth Circuit easily dismissed the agency’s argument that its “[r]egulation targets only those” participants who violate the statute, not the plaintiffs, “who purportedly do not.” *Id.* Even though the plaintiffs did not intend to violate the statute, they were still subject to the inspection procedures and had to participate under threat of the sanctions. *Id.* That made the plaintiffs objects of the regulation and subject to an increased regulatory burden—even if they never violated the statute and never were sanctioned. *See id.*

Defendants suggest (at 2–4) that Dr. Purl must show more beyond the indisputable fact that the 2024 Rule requires and forbids some action from her, such as a certainty that a minor will enter her clinic having obtained an abortion or gender transition she cannot report. That is incorrect. “[T]he fact that the Plaintiffs are now subject to regulations that are contrary to law *is itself a concrete injury* sufficient to give them standing.” *Tex. Med. Ass’n v. HHS*, 110 F.4th 762, 773 (5th Cir. 2024) (emphasis added). Just as the *Contender Farms* plaintiffs did not need to show they would be sanctioned under the challenged procedures, *see* 779 F.3d at 266, Dr. Purl need not show she will be prevented from disclosing PHI because of the 2024 Rule. The regulation’s function of requiring and forbidding some action by Dr. Purl is *itself* a concrete and particularized injury under Article III, and a “legal wrong” and “adverse[] affect[]” under 5 U.S.C. § 702. “So in those cases, standing is usually easy to establish.” *All. for Hippocratic Med.*, 602 U.S. at 382.

As the Eighth Circuit recently explained, “[t]he imposition of a regulatory burden itself causes injury.” *Tennessee v. EEOC*, 129 F.4th 452, 458 (8th Cir. 2025). The court added that it was following the Supreme Court’s approach in *West Virginia v. EPA*, 597 U.S. 697 (2022). There the Supreme Court had allowed plaintiff states to sue because they were “the object” of an EPA regulation’s

“requirement,” and the Supreme Court “deemed it unnecessary to consider whether the requirement caused any specific economic harms” to the plaintiffs on top of their being directly regulated. *Tennessee v. EEOC*, 129 F.4th at 458 (cleaned up) (discussing *West Virginia*, 597 U.S. at 719).

This is a well-settled APA doctrine. For example, at oral argument in *Corner Post, Inc. v. Board of Governors of Federal Reserve Systems*, 603 U.S. 799 (2024), Justice Kavanaugh asked counsel for the United States whether, as a matter of “Article III standing,” on “the day a rule is adopted [if] you’re a regulated party, even if nothing’s happened to you by the agency, you have standing to go in to sue.” The Assistant to the Solicitor General said, “[t]hat’s my understanding too, yes.” Justice Kavanaugh followed up, asking, “if you’re not a regulated party but[] you’re an affected party ... you also ... have standing to sue an injury on the day the rule is promulgated?” And counsel said, “I agree with that too.”⁷

Courts widely agree. Standing is “self-evident” for the object of a regulation, and “no evidence outside the administrative record is necessary.” *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002). “[B]eing subject to” a regulation requiring action constitutes sufficient harm to confer standing, because the party is “directly regulated.” *Carman v. Yellen*, 112 F.4th 386, 407 (6th Cir. 2024). If plaintiffs are “directly regulated, there [is] no doubt that [their] interests were within the regulated zone” for standing to seek review. *Cotovsky-Kaplan Physical Therapy Assocs., Ltd. v. United States*, 507 F.2d 1363, 1366 (7th Cir. 1975). “As the *Lujan* Court explained, a plaintiff is presumed to have constitutional standing to seek injunctive relief when it is the direct object of regulatory action challenged as unlawful.” *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 655 (9th Cir. 2011).

⁷ Oral Argument, *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, No. 22-1008, 2024 WL 712351, at *69 (U.S. Feb. 20, 2024).

As Plaintiffs have already shown, Defendants’ argument that the 2024 Rule does not function the way Dr. Purl reads it—repeated in their opposition brief (at 2–3)—is a merits issue that is not relevant to whether she has standing. *See* Pls.’ Opp. at 8–9 (citing, *e.g.*, *OCA-Greater Hous. v. Texas*, 867 F.3d 604, 613 (5th Cir. 2017), *Duarte ex rel. Duarte v. City of Lewisville*, 759 F.3d 514, 520 (5th Cir. 2014), and *FEC v. Cruz*, 596 U.S. 289, 298 (2022)). Defendants’ attempt to contort the language of the 2024 Rule to avoid this lawsuit is unavailing.

But in any event, the 2024 Rule does contradict the rule of construction in 42 U.S.C. § 1320d-7(b). HIPAA cannot “be construed to invalidate or limit” public health activities, including abuse reporting and “public health investigation[s].” 42 U.S.C. § 1320d-7(b); *see* Pls.’ Opp. at 13–18; Mem. Op. & Order, *Purl v. HHS*, No. 2:24-CV-228-Z, 2024 WL 5202497, at *6–7 (N.D. Tex. Dec. 22, 2024), ECF No. 34. But under the 2024 Rule, for example: A report of abuse cannot be based “solely” on “lawful ‘reproductive health care.’” Pls.’ Opp. at 15 (quoting 89 Fed. Reg. at 33,004). Unborn children cannot be protected, regardless of state law. *Id.* And the 2024 Rule can block an investigation into conduct that law enforcement “‘reasonably believes’” was unlawful. *Id.* at 17 (quoting 89 Fed. Reg. at 32,993). These are not mere “‘incidental effect[s].” Defs.’ Br. at 20–21; *see also* Proposed Intervenor’s Br. [ECF No. 69] at 6 (“the barest of impacts”). So even if § 1320d-7(b) prohibits HIPAA regulations that “preempt or supersede” state procedures, as Defendants put it (Defs.’ Br. at 20–21), or that “substantial[ly] impair[]” or “nullify” reporting and investigative authority, as the proposed intervenors put it (at 5 & n.2), the 2024 Rule flouts the rule of construction.

B. Plaintiffs’ compliance costs are also an injury in fact.

Defendants also attempt to dismiss Dr. Purl’s compliance costs—which independently prove standing—but that argument is again unsuccessful. The 2024 Rule *admits* it imposes compliance costs on entities like Dr. Purl and the Clinic, 89 Fed. Reg. at 32,979; Dr. Purl has more than amply testified to those costs, Purl Decl. ¶¶ 15–18, App. 005–06, ECF No. 46; and pecuniary harm is a quintessential injury in fact. *See Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017) (“[f]or standing purposes, a loss of even a small amount of money is ordinarily an ‘injury.’”); *Career Colleges & Schs. of Tex. v. U.S. Dep’t of Educ.*, 98 F.4th 220, 234 (5th Cir. 2024) (cleaned up), *cert. granted in part*, No. 24-413, 2025 WL 65914 (U.S. Jan. 10, 2025) (injury in fact established where the regulation would require “at least some degree of preparatory analysis, staff training, and reviews of existing compliance protocols”); *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 310 (5th Cir. 2023) (similar).

II. The Court should set aside (vacate) the 2024 Rule nationwide.

Without defending the 2024 Rule on its merits, the agency argues against the default remedy, vacatur, and says relief should be limited to Dr. Purl and the Clinic. *See* Defs.’ Opp. at 4–11. These arguments are misplaced. The Court should vacate this unlawful regulation that the agency declines to defend.

A. Vacatur is the default remedy for unlawful agency action.

First, Defendants argue (at 4–5) that vacatur is not mandatory. Fifth Circuit precedent says otherwise: the APA “empowers and *commands* courts to set aside unlawful agency actions.” *Tex. Med. Ass’n*, 110 F.4th at 779 (emphasis added) (cleaned up); *see also Texas v. United States*, 126 F.4th 392, 418 (5th Cir. 2025). At any rate, even the case Defendants cite emphasizes that vacatur is the default APA remedy. Defs.’ Opp. at 5, 6–7 (citing *Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir.

2023), *aff'd*, 602 U.S. 406 (2024)); *see also* Pls.' Br. at 39–40; Pls.' Opp. at 32–34.

Defendants thus have the burden to show vacatur would be improper here.

Cargill is not to the contrary. The district court there upheld the agency action. 57 F.4th at 457. The Fifth Circuit reversed, finding the regulation unlawful, and remanded on remedy because (unsurprisingly) “the parties ha[d] not briefed the remedial-scope question.” *Id.* at 472. So contrary to Defendants' theory (at 5, 6–7 n.3), such a remand is no support for deviating from the default rule here.

Defendants imply (at 7–8) that remand to the agency without vacatur might be appropriate. That is not a viable option here because regulated entities would have to comply with this incomprehensible rule in the meantime. *See* Pls.' Opp. at 33–34. Remand without vacatur can be appropriate only where a procedural infraction is not serious and vacatur would be disruptive. *Cf. Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993). The opposite is true here: the 2024 Rule is flawed for many reasons. And vacatur would not be disruptive, as HIPAA functioned for over 20 years without these new gerrymandered categories and arcane rules designed to protect procedures politically favored by the previous administration. *See* 2024 WL 5202497, at *10, ECF No. 34. Nor is the process for replacing the regulation a speedy one. And as seen by proposed intervenors' contentions, any new rule by this administration is likely to be challenged and possibly enjoined by another court before it goes into effect. Plaintiffs should not be forced to wait years before they receive relief.

Plus, Defendants have elected not to defend the 2024 Rule on its merits, even as to procedural deficiencies, so there is no way to justify an exception to the default rule. Remand without vacatur requires “a serious possibility” of the agency remedying procedural problems on remand, *Texas v. United States*, 50 F.4th 498, 529 (5th Cir. 2022), but Defendants do not suggest that is possible here.

B. A vacated regulation is void as to everyone, not just the parties.

Defendants next argue vacatur could be limited to Plaintiffs alone, leaving the 2024 Rule in effect as to every other HIPAA-regulated entity in the country. Their citation (at 5) to *Texas v. United States*, 126 F.4th at 420–22, does not support the proposition. There, the Fifth Circuit limited the scope of an *injunction* to Texas because that remedied the injuries shown. *Id.* at 421. Unlike an injunction, vacatur operates against the agency action—*in rem*—and thus “render[s the] agency[’s] action void.” *Id.* at 418 (cleaned up). A void regulation cannot have force against anyone. *See Corner Post*, 603 U.S. at 830 (Kavanaugh, J., concurring). An injunction, by contrast, is an *in personam* equitable remedy, so it runs between the parties. Indeed, Defendants implicitly acknowledge elsewhere that vacatur *cannot* be tailored in the way an injunction can. *See* Defs.’ Opp. at 8 (“injunctive relief, as opposed to vacatur, ... could be tailored to prevent the Rule’s application only in the context that gives rise to Dr. Purl’s injuries”).

Defendants also contend (at 5–6) that plaintiff-only relief would be enough to remedy Plaintiffs’ injuries, so “any broader relief would contradict constitutional and equitable limitations on this Court’s remedial authority.” To support this proposition, Defendants cite precedent addressing the equitable powers granted to federal courts since the Judiciary Act of 1789, not remedies under the APA. *Grupo Mexicano de Desarrollo, S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308 (1999), stands for the proposition that the All Writs Act gives a federal court equitable power to issue only remedies that were “traditionally accorded by courts of equity” in 1789. *Grupo Mexicano*, 527 U.S. at 319. Same with *Trump v. Hawaii*, 585 U.S. 667 (2018). *See* Defs.’ Opp. at 6 (quoting 585 U.S. at 717 (Thomas, J., concurring)). That proposition is undisputed here, but it is irrelevant to APA vacatur. Defendants’ remaining quotes come from the Supreme Court’s cautionary words about

proving Article III standing in a case under 42 U.S.C. § 1983, *Gill v. Whitford*, 585 U.S. 48, 72–73 (2018), and narrowing a state-court injunction that infringed on First Amendment rights, *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). Section 1983 claims and First Amendment defenses do not say much, if anything, about the scope of APA relief.

Unlike a court sitting in equity, a court reviewing agency action under the APA is “‘empower[ed] ... to act directly against the challenged agency action.’” *Corner Post*, 603 U.S. at 838 (Kavanaugh, J., concurring) (quoting Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 1012 (2018)). For the same basic reason, Fifth Circuit precedent recognizes that vacatur “is not party-restricted and allows a court to ‘set aside’ an unlawful agency action.” *Career Colleges*, 98 F.4th at 255. When it does so, the court “vacate[s the] agency action[] in the same way that appellate courts vacate the judgments of trial courts.” *Corner Post*, 603 U.S. at 838 (Kavanaugh, J., concurring). That means the agency action is simply “‘treated as though it had never happened.’” *Griffin v. HM Fla.-ORL, LLC*, 144 S. Ct. 1, 2 n.1 (2023) (quoting Mitchell, *The Writ-of-Erasure Fallacy*, at 1012–13 (footnote omitted)) (Kavanaugh, J., statement respecting the denial of application). By contrast, courts reviewing statutes and sitting in equity “enjoy the power to enjoin individuals tasked with enforcing laws, not the laws themselves.” *Whole Woman’s Health v. Jackson*, 141 S. Ct. 2494, 2495 (2021) (per curiam).

C. A party-specific remedy would not provide complete relief.

But even if vacatur could theoretically be party specific, barring these federal agencies from enforcing the 2024 Rule would not be enough to remedy all Plaintiffs’ proven harm. That’s for three reasons.

First, Plaintiffs regularly exchange PHI with other medical providers, such as hospitals, or disclose it to business associates, such as insurance companies and

software providers. *See* Pls.’ Opp. at 37–38. This is no surprise, because the whole impetus for HIPAA (indeed, the “P” in the statutory title) is “portability”—“to enable health information to be exchanged electronically” in an interconnected health system. 42 U.S.C. § 1320d-2(a)(1). The agency’s own amici emphasize this.⁸

So Defendants’ proposed remedy would be unworkable. Dr. Purl and her Clinic could not care for patients in an interconnected health system where the 2024 Rule not only gerrymanders information privacy based on the government favoring abortions and gender transitions, but also applies to Dr. Purl’s business associates—and any business she seeks to work with in the future—but not to her. Dr. Purl’s patients, too, would face obstacles where they exercise their HIPAA right to transfer information to or from Dr. Purl and other doctors, but different sets of HIPAA rules apply on either side of that transfer. The Department acknowledged the need for uniformity in this very regulation. *See* 89 Fed. Reg. at 32,987–88. To provide full relief, the remedy must apply to every external healthcare system and business entity with which Plaintiffs interact—including those they will encounter in the future. An illegal HIPAA regulation cannot be valid as to other hospitals and doctors in North Texas but invalid as to Dr. Purl. This alone shows that vacatur is inherently universal.

Second, Defendants’ preferred remedy would not stop state attorneys general from pursuing enforcement actions for violating the 2024 Rule. *See* 42 U.S.C. § 1320d-5(d). PHI regularly crosses state lines, as HHS emphasizes. *See* 89 Fed. Reg. at 32,987–88. An injunction that binds only the federal government is no

⁸ *See* Amicus Brief of American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine [ECF No. 88] at 14–16.

Contrary to amici’s characterization (at 21), this case challenges the 2024 Rule, not the Privacy Rule as it existed before. As the Court has noted, “the Privacy Rule already protects reproductive healthcare information the same as *all other* sensitive medical information.” 2024 WL 5202497, at *10, ECF No. 34.

protection from an enforcement action brought by, for example, the Attorney General of New Mexico. *See* Pls.’ Opp. at 38.

Finally, an injunction on enforcement against Dr. Purl and her Clinic would not work because of the 2024 Rule’s interference with state law enforcement. The state cannot be subject to the 2024 Rule’s illegal attestation requirements for some doctors but not for Dr. Purl. Only vacatur would make the 2024 Rule inapplicable on both sides of state enforcement and public health investigations. In contrast, a bare prohibition on Defendants enforcing the 2024 Rule against Dr. Purl and her clinic—but leaving it in force as to everyone else—would not provide complete relief, because the point of this illegal rule is to stop doctors and states from talking *to each other*. *Contra* Defs.’ Opp. at 6, 10–11. Whether vacatur or an injunction on enforcement, the remedy cannot be limited to Plaintiffs alone.

That preliminary relief has been limited to Plaintiffs does not change the result. Preliminary relief under the APA allows for balancing the equities in a way that vacatur at final judgment does not. *Compare* 5 U.S.C. § 705, *with id.* § 706(a); *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 952 (5th Cir. 2024), *cert. granted*, No. 24-316, 2025 WL 65913 (U.S. Jan. 10, 2025) (“[W]e do not read our precedent to require consideration of the various equities at stake” when vacating agency action). And even if equitable considerations were relevant to vacatur, there is now more evidence showing that a plaintiff-specific remedy would not provide complete relief. Indeed, this Court’s expedited summary judgment schedule implicitly acknowledges that the preliminary relief is not a long-term fix. A limited injunction on enforcement may have sufficed to maintain the status quo until this motion is resolved, but it is not workable for permanent relief.

And vacating the 2024 Rule would not “trench on the review of other plaintiffs’ challenges to the Rule that are pending in other courts.” Defs.’ Opp. at 7. To the contrary, “courts routinely grant follow-on injunctions against the [federal

g]overnment, even in instances when an earlier nationwide injunction” has been issued. *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 59–60 (D.D.C. 2020) (collecting cases). The same is true of vacatur—this Court’s judgment vacating the 2024 Rule would not stop other courts from resolving other challenges to its lawfulness. *See, e.g.,* Order, *Carroll ISD v. U.S. Dep’t of Educ.*, No. 4:24-cv-00461-O (N.D. Tex. Feb. 19, 2025), ECF No. 86 (vacating the final Title IX rule that had been recently vacated in *Tennessee v. Cardona*, No. 2:24-cv-072-DCR, 2025 WL 63795, at *5–7 (E.D. Ky. Jan. 9, 2025), *as amended* (Jan. 10, 2025) (Reeves, J.)). And that makes sense. A district court’s judgment vacating a regulation does not moot other APA challenges until the completion of all appeals or lapse of the appeal deadline.⁹ Until then, other challengers risk having the unlawful agency action reimposed because of reversal on appeal in a stranger’s case.

Finally, turning to Plaintiffs’ alternative request for a permanent injunction, Defendants say (at 10) that Plaintiffs cannot get an injunction beyond “how the Rule allegedly restricts the reporting of child abuse under Texas law.” They base that theory on the proposition that “[t]he propriety and form of an equitable remedy are determined by ‘the nature of the violation’ established.” Defs.’ Opp. at 10 (quoting *Swann v. Charlotte-Mecklenburg Bd. of Educ.*, 402 U.S. 1, 16 (1971)). To be sure, as the Supreme Court observed in *Swann*, “[in] any equity case, the nature of the violation determines the scope of the remedy.” 402 U.S. at 16. The parties here don’t disagree about that legal principle—they disagree (at most) about “the nature of the violation” in this case. *Id.* And interference with reporting child abuse is not the only deficiency in the 2024 Rule. The rule also limits public health data inquiries, it illegally changes definitions of person and public health, it requires

⁹ The Department of Justice recently recognized as much. *See* Joint Status Report, *Carroll ISD v. U.S. Dep’t of Educ.*, No. 4:24-cv-00461-O (N.D. Tex. Feb. 17, 2025), ECF No. 85.

Dr. Purl to screen PHI each time a disclosure is considered to determine whether the 2024 Rule applies, and it imposes an esoteric system of legal presumptions and attestations.

A case that Defendants quote (at 10) shows why Plaintiffs are entitled to wider relief if the Court issues an injunction instead of vacatur. *Lewis v. Casey*, 518 U.S. 343 (1996), is a leading case on the relationship between Article III standing and remedies. *Id.* at 349. Any remedy “must of course be limited to the inadequacy that produced the injury in fact that the plaintiff has established.” *Id.* at 357. Here, the threat that Plaintiffs will be unable to comply with Texas reporting obligations is just one of the injuries in fact suffered here. Rather, Plaintiffs are subject to—and thus injured by—the entire 2024 Rule. Because every provision and application of the 2024 Rule is an increased regulatory burden and must be incorporated into the Clinic’s policies, every provision and application is its own injury in fact. HIPAA does not authorize HHS to interfere with state public-health procedures, *see* Pls.’ Br. at 19–23, redefine statutory terms, *see id.* at 25–29, or impose content-based conditions for PHI reflecting its favored medical issues, *see id.* at 30–33; Pls.’ Opp. at 21–25. Because every provision and application of the 2024 Rule is contrary to law (*cf. infra* at III.A), Plaintiffs are entitled to relief against every provision and application.

If the 2024 Rule is not vacated, Plaintiffs have no alternative form of relief for this unlawful increased regulatory burden, so they would be entitled to an injunction completely protecting them from the effects of the 2024 Rule. And as discussed above, prohibiting Defendants (but not state attorneys general) from enforcing the 2024 Rule against Plaintiffs (but not other medical providers or business associates) would not provide complete relief for the violations shown.

III. Severability doctrine does not save any “reproductive health care” provisions.

Defendants generically argue (at 8–9) that the 2024 Rule’s provisions are severable. But every provision from the “reproductive health care” proposed rule implements the regime the Court found to be unlawful. The only possible exception (and the only one Defendants mention) relates to *some* paragraphs in 45 C.F.R. § 164.520—the ones derived from a separate proposed rule regulating substance use disorder treatment records. *See* 87 Fed. Reg. 74,216 (proposed Dec. 22, 2022). Defendants cannot show any other provisions should be severed from vacatur.

A. Plaintiffs have challenged every substantive provision of the 2024 Rule.

Contrary to Defendants’ characterization (at 9), this is not a challenge to a mere “handful of provisions” in the 2024 Rule. The entire 2024 Rule focuses on special rules for RHC. It inserts five substantive regulatory provisions and adds a perfunctory severability clause. *See* 89 Fed. Reg. at 33,062–66. Each substantive provision is there to drive the 2024 Rule’s illegal RHC agenda.

45 C.F.R. § 160.103. The 2024 Rule “[r]evis[es] the definition of ‘Person’” and adds “the definitions of ‘Public health’ and ‘Reproductive health care.’” 89 Fed. Reg. at 33,062–63 (amending 45 C.F.R. § 160.103). These changes were designed to carve the unborn out of HIPAA and RHC out of legitimate public health measures and are illegal. Pls.’ Br. at 25–29; *see* Compl. [ECF No. 1] ¶¶ 32–33, 64–68, 91–92, 119–20, 136.

45 C.F.R. § 164.502. The 2024 Rule adds the “prohibited purpose” provision—the heart of the new “reproductive health care” regime. 89 Fed. Reg. at 33,063 (amending 45 C.F.R. § 164.502(a)(5)). And it adds a special rule for personal representative status when it comes to “reproductive health care” decisions. 89 Fed. Reg. at 33,063 (modifying 45 C.F.R. § 164.502(g)(5); *see id.* at 33,026 (provision

“clarif[ies] that it is not reasonable to elect not to treat a person as [a patient’s] personal representative because the person provides or facilitates reproductive health care for and at the request of the [patient]”). These content-based rules for RHC are unlawful. Pls.’ Br. at 19–25, 30–39; Pls.’ Opp. at 21–25; *see* Compl. ¶¶ 50–63, 94–96, 114–39.

45 C.F.R. § 164.509. The 2024 Rule requires an attestation from the requesting law enforcement official before a doctor may disclose PHI that is “potentially related to reproductive health care.” 89 Fed. Reg. at 33,063–64 (adding 45 C.F.R. § 164.509). This, too, is at the core of the 2024 Rule’s illegality. Pls.’ Br. at 19–23, 38–39; *see* Compl. ¶¶ 70–73, 95, 117, 132–137.

45 C.F.R. § 164.512. The 2024 Rule revises the Privacy Rule’s permissions to incorporate its new “reproductive health care” rules. 89 Fed. Reg. at 33,064 (amending 45 C.F.R. § 164.512). These changes are likewise unlawful. Pls.’ Br. at 30–37; Pls.’ Opp. at 21–25; *see* Compl. ¶¶ 117–18, 95, 121–24.

45 C.F.R. § 164.520. The 2024 Rule requires covered entities to add information about its RHC provisions to their notices of privacy practices. 89 Fed. Reg. at 33,064–66 (amending 45 C.F.R. § 164.520); *see* 45 C.F.R. § 164.520(b)(1)(ii)(F), (G), (H)). This provision, too, implements the illegal RHC regime. Pls.’ Br. at 30–37; *see* Compl. ¶¶ 117–18, 100, 121–24.

Finally, the 2024 Rule adds a boilerplate severability clause: “If any provision of the [2024 Rule] is held to be invalid or unenforceable ... it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable” 89 Fed. Reg. at 33,066 (adding 45 C.F.R. § 164.535). This provision has no function on its own, and it cannot substitute for the government’s obligation to show that each provision it wants severed is actually severable from the illegal aspects of the 2024 Rule.

B. Plaintiffs would not object to severing those portions of 45 C.F.R. § 164.520 derived from a separate proposed rule addressing substance-use-disorder records.

Defendants point out (at 9), however, that some lines of the final rule implemented a different and separate proposed rule not about RHC, but about substance use disorder provisions in the CARES Act, 42 U.S.C. § 290dd-2. *See supra* n.4, 87 Fed. Reg. 74,216.¹⁰ Far from “just one example,” Defs.’ Opp. at 9, this is Defendants’ only plausible claim for severability. Unfortunately, Defendants have offered no “briefing or argument ... on the consequences of a partial [vacatur or] injunction.” *Louisiana v. United States Dep’t of Educ.*, No. 24-30399, 2024 WL 3452887, at *2 (5th Cir. July 17, 2024). An unadorned citation to a boilerplate severability clause is not enough. They do not even identify which revisions to § 164.520 could stand apart from the 2024 Rule’s RHC regime. This “vague attempt to limit ultimate relief” does not satisfy severability doctrine. *See Louisiana*, 2024 WL 3452887, at *1.

As best Plaintiffs can tell, however, the following changes to § 164.520 originated in the substance-use-disorder proposal:

- New paragraphs: (a)(2), (b)(1)(iii)(D), (b)(1)(iii)(E), and (d)(4);
- A new clause in paragraph (b)(1) (referring to 42 U.S.C. § 290dd-2);
- Adding a reference to 42 C.F.R. part 2 in paragraphs (b)(1)(ii)(C) and (D);
- Adding the words “and (B)” in paragraph (b)(1)(iii);
- Removing the words “with respect to protected health information” from paragraph (b)(1)(v)(A).

See 89 Fed. Reg. at 33,045–48 (discussing 87 Fed. Reg. at 74,237–38, 74,286–87).

¹⁰ That Congress created special protections for substance-use-disorder treatment records is further evidence that HHS lacks authority to create content-based privacy requirements by regulation. *See* Pls.’ Opp. at 23–24.

Taking Defendants to say that HHS would have made these changes to § 164.520 even without the RHC regime, and that it finalized them in the 2024 Rule as a matter of administrative convenience, these revisions could meet the severability standard. *See Texas v. United States*, 126 F.4th at 418. Defendants do not cite it, but HHS seems to have contemplated this scenario. 89 Fed. Reg. at 33,048. To illustrate the severability provision in action, HHS said that “changes ... to the [notice of privacy practices] requirements in 45 CFR 164.520 (including the changes finalizing proposals from the 2022 Part 2 NPRM),” for example, “shall remain in full force and effect to the extent that they are not directly related to a provision in this rulemaking that is held to be invalid or unenforceable such that notice of that provision is no longer necessary.” *Id.* Plaintiffs would not object to final judgment severing these changes to § 164.520—and only these changes—while vacating the rest of the 2024 Rule.

But not all changes to § 164.520 are disconnected from the RHC regime, so some revisions to § 164.520 are not severable. *First*, the 2024 Rule says notices of privacy practices must include “[a] description, including at least one example, of the types of uses and disclosures prohibited under § 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition.” 45 C.F.R. § 164.520(b)(1)(ii)(F). Section 164.502(a)(5)(iii) is the “prohibited purpose” provision at the heart of the 2024 Rule’s “reproductive health care” regime. *Second*, they must include “[a] description, including at least one example, of the types of uses and disclosures for which an attestation is required under § 164.509.” *Id.* § 164.520(b)(1)(ii)(G). *Third*, there must be “[a] statement adequate to put the individual on notice of the potential for information disclosed pursuant to this subpart to be subject to redisclosure by the recipient and no longer protected by this subpart.” *Id.* § 164.520(b)(1)(ii)(H). These paragraphs, too, are part of the RHC regime. *See* 89 Fed. Reg. at 33,046.

These new paragraphs were proposed with the rest of the RHC provisions. *See* 88 Fed. Reg. at 23,539. The agency acknowledges that the changes are about RHC: The “[n]ew paragraphs ... provide individuals with additional information about how their PHI may or may not be disclosed for purposes addressed in this rule, furthering trust in the relationship between regulated entities and individuals by ensuring that individuals are aware that certain uses and disclosures of PHI are prohibited.” 89 Fed. Reg. at 33,046. Relief must extend to § 164.520(b)(1)(ii)(F), (G), and (H), even if other revisions to § 164.520 are severed.

CONCLUSION

The Court should grant Plaintiffs’ motion for summary judgment and vacate or enjoin enforcement of the 2024 Rule as set out above.

Respectfully submitted this 17th day of March 2025.

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